UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION, Plaintiff, v. MICHAEL FRIEDMAN, in his official capacity as Acting Commissioner, Food and Drug Administration, and DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services, Defendants.	)	Civil Action 94-1306 (RCL)

MEMORANDUM OPINION

This matter comes before the Court on defendants' motion to alter or amend the judgment and for a stay. Upon consideration of the motion, plaintiff's opposition thereto, defendants' reply, and the entire record in this case, the defendants' motion will be GRANTED in part and DENIED in part, and the parties will be directed to submit supplemental briefs as specified by the Court.

I. FACTS

On July 30, 1998, this Court granted plaintiff Washington Legal Foundation's (WLF) motion for summary judgment against the federal defendants Friedman and Shalala, representing the Food and Drug Administration and the Department of Health and Human

Services, respectively. Having found that the defendants' policies violated the First Amendment to the United States Constitution, the Court entered judgment against the defendants and issued a permanent injunction barring them from "application or enforcement of any regulation, guidance, policy, order or other official action" that placed certain unconstitutional restrictions on the commercial speech of drug and device manufacturers. In particular, the Court stated that

1. Defendants SHALL NOT in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:

a) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previously published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on uses of drugs or medical devices other than those approved by FDA and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;

b) from disseminating or redistributing to physicians or other medical professionals any reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are

normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on uses of drugs or medical devices other than those approved by FDA; or

c) from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium, regardless of whether uses of drugs and medical devices other than those approved by FDA are to be discussed.

Order Granting Summary Judgment and Permanent Injunction, Washington Legal Found. v. Friedman, 13 F.Supp.2d 51, 74-75 (D.D.C. 1998).

On August 13, 1998, defendants filed a Rule 59(e) motion to alter or amend the judgment and for a stay, which is now before the Court. In their motion, the defendants request that the Court amend the July 30, 1998 order and injunction in two ways: (1) to clarify that the injunction applies only to unapproved uses of drugs or devices approved by the FDA for some other use, not to drugs or devices that have not received FDA approval for any use; and (2) to restrict the scope of the order to the three Guidance Documents discussed in the Court's opinion. In response to the motion to alter or amend, the plaintiff has consented to the first proposed amendment clarifying that the order and injunction applies to unapproved uses of approved drugs, but the plaintiff opposes the second amendment.

The first proposed amendment will be granted. The second proposed amendment, however, will be denied, and the parties will be directed to submit supplemental briefs on the extent to which the injunction may affect recently effective legislation and regulations.

II. DISCUSSION

The defendants contend that the July 30, 1998 order goes beyond the underlying Memorandum Opinion, and the issues presented in the litigation, in that it is not confined to the three Guidance Documents that were in effect at the time the order and injunction was issued. In particular, the defendants are concerned that the injunction might apply to Section 401 of the Food and Drug Administration Modernization Act (FDAMA) and its implementing regulations, both of which went into effect on November 21, 1998, after this Court's July 30, 1998 decision and injunction.

To begin with, the defendants are mistaken about the intended scope of the Court's opinion and injunction. The Court's Memorandum Opinion, while focusing on the concrete provisions of the Guidance Documents, was intended to apply to the policies underlying the Guidance Documents.[1] This was the

[1]Although the defendants argue that the order should be confined to the Guidance Documents, their own words belie their understanding of the scope of the Court's decision. See, e.g., Memo. Pts. & Auths. Supp. Defs.' Mot. at 2 ("The Court

position taken by the plaintiff in its complaint, and it was the understanding of the Court throughout the litigation.

The Court's decision and injunction must be read to apply to the underlying policies of the FDA, and not merely to the express provisions of the Guidance Documents, given the history of the policies at issue, which have been expressed in various documents over the years. Before the 1980's, the FDA did not attempt to regulate the dissemination by drug and device manufacturers of scientific and medical information concerning unapproved uses of FDA-approved drugs.[2] In the 1980's, however, drug manufacturers began to devote increasingly large resources to sponsoring continuing medical education (CME) courses, especially when those courses concerned off-label uses of their drugs. Concerns about this sponsorship as a promotional practice led to Congressional hearings in 1990. In response, the FDA developed a Draft Concept Paper attempting to set forth the circumstances under which a manufacturer could properly sponsor scientific and educational programs that addressed off-label uses, but this paper only heightened the confusion surrounding the issue. In 1992, the FDA published a Draft Policy Statement on Industry Supported

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determined, however, that the policies expressed in the Guidance Documents are more extensive than necessary to accomplish the government's legitimate purposes, and thereby impermissibly burden speech.") (Emphasis added.)

[2]Because such unapproved uses do not appear on the official label of a drug or device, they are commonly referred to as "off-label" uses.

Scientific and Educational Activities, 57 Fed. Reg. 56412 (1992), which again tried to describe the relevant factors in determining when a manufacturer-supported activity improperly promotes off-label uses. After the required comment period, the FDA revised the Draft Policy Statement and published its Final Guidance on Industry Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (1997), which identifies twelve factors to be used in determining the propriety of manufacturer sponsorship of CME and similar programs. This Guidance is one of those found unconstitutional by the Court last July. Unlike the other policies at issue, though, the FDA's CME policy does not appear to be affected by the FDAMA and its implementing regulations.

Around 1992, the FDA also began for the first time to regulate manufacturers' dissemination of scientific and medical literature that discusses off-label uses of the manufacturers' products. Initially, the FDA's policy was set forth informally by means of letters to individual drug manufacturers warning them against reproducing or distributing scientific and medical articles and texts that discussed off-label uses of their drugs. These policies[3] also were eventually compiled and published as the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Date, 61 Fed. Reg. 52800 (Oct. 8, 1996), and the Guidance for Industry Funded Dissemination of Reference

[3]The FDA's policies differ slightly as to dissemination of articles and dissemination of reference texts.

Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996). Unlike the CME Giudance, the policies expressed in these two Guidance Documents, which the Court held unconstitutional last year, appear to be largely perpetuated by the FDAMA.

At the time of this Court's July 30, 1998 order and permanent injunction, the FDAMA had been enacted but had not yet gone into effect. The Court was made generally aware of its provisions by the parties, and the Court explicitly noted that "the October 1996 Guidance Documents will be superseded by statute [upon the taking of effect of the FDAMA.]" Washington Legal Foundation, 13 F. Supp. 2d at 58-59. Clearly, it was not the Court's intention that the implementation of the new legislation would render its decision moot. On the contrary, the Court was aware that the Guidance Documents represented only the latest articulation of the FDA's ongoing policies toward dissemination of scientific and educational information to health care providers. Consequently, while focusing on the Guidance Documents as the most recent available articulation of the policies, the Court considered the underlying policies in evaluating the constitutionality of the FDA's position on manufacturer-sponsored dissemination of medical information. As set forth in both the Memorandum Opinion, see id. at 54, and in the order and injunction, see id. at 74-75, the Court found that the FDA's policies imposed an unconstitutional burden upon the plaintiff's First Amendment rights. Consequently, the Court will

not amend the July 30, 1998 order and permanent injunction to limit it to the three Guidance Documents. Such limitation was never the Court's intention.

This clarification, while it fully disposes of the defendants' motion, does not fully dispose of defendants' concern, for the following reason. On November 21, 1998, the FDAMA became effective and the defendants issued final regulations implementing that legislation. Those regulations were properly promulgated at the time, regardless of the interpretation of the July 30, 1988 order and injunction, because that order and injunction was stayed by agreement of the parties pending resolution of the Rule 59 motion decided today. Had the Court agreed to restrict the injunction to the three Guidance Documents, then the FDAMA and its implementing regulations would have been entirely unaffected by the injunction. The Court, of course, will not so restrict the injunction, and so the issue of the FDAMA and its implementing regulations remains.

While the Court has ruled definitively on the FDA <u>policies</u> described in the July 30, 1998 Memorandum Opinion and the order and injunction, the extent to which the FDAMA and its implementing regulations perpetuate those policies has not been adjudicated. The Court agrees that such a determination should not be made without the benefit of specific briefing by all parties. Therefore, the Court will defer the entry of final judgment in this action to allow the parties to submit

supplemental briefs directed at the FDAMA, its implementing regulations, and the extent to which these provisions may be consistent or inconsistent with the Court's July 30, 1998 order and injunction. A briefing schedule will be set forth in the separate order issued this date.

III. CONCLUSION

For the reasons set forth above, the defendants' motion to alter or amend the judgment and for a stay will be GRANTED in part and DENIED in part. The July 30, 1998 order and permanent injunction will be amended to clarify that it applies only to unapproved uses of FDA-approved drugs and devices, not to unapproved drugs and devices. It will not be amended, however, to limit its application strictly to the three Guidance Documents. The parties shall submit supplemental briefs addressing the issues raised by the recently effective FDAMA and its implementing regulations, as ordered by the Court.

A separate order will issue this date.

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Royce C. Lamberth
DATE: United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WASHINGTON LEGAL FOUNDATION, Plaintiff, v. MICHAEL FRIEDMAN, in his official capacity as Acting Commissioner, Food and Drug Administration, and DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services, Defendants.	)	Civil Action 94-1306 (RCL)

REDLINE AMENDED ORDER GRANTING SUMMARY JUDGMENT AND PERMANENT INJUNCTION

This action is before the Court on the Cross-Motions for Summary Judgment filed by Plaintiff Washington Legal Foundation ("WLF") and defendants Michael A. Friedman and Donna Shalala.

Having reviewed the memorandum and other materials submitted, having heard oral argument and otherwise being fully advised;

THE COURT FINDS that there are no genuine issues of material fact and that WLF is entitled to judgment as a matter of law; accordingly,

THE COURT GRANTS WLF's Motion for Summary Judgment;

THE COURT DENIES Defendants' Cross-Motion for Summary Judgment;

THE COURT FINDS AND DECLARES that the policies, rules and regulations of the United States Food and Drug Administration ("FDA") set forth in the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Reprint Guidance"), Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996) (the "Textbook Guidance"), and Final Guidance on Industry Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (Dec. 3, 1997) (the "Final CME Guidance") are contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.

THE COURT HEREBY ENJOINS Defendants, their successors, an all persons acting in concert with them or otherwise purporting to act on behalf of the United States (collectively "Defendants") from application or enforcement of any regulation, guidance, policy, order or other official action , as follows:

2. Defendants SHALL NOT in any way prohibit, restrict, sanction or otherwise seek to limit any pharmaceutical or medical device manufacturer or any other person:

d) from disseminating or redistributing to physicians or other medical professionals any article concerning prescription drugs or medical devices previous published in a bona fide peer-reviewed professional journal, regardless of whether such article includes a significant or exclusive focus on ~~uses of~~ unapproved uses for drugs or medical devices ~~other than those~~ that are approved by FDA for other uses and regardless of whether such article reports the original study on which FDA approval of the drug or device in question was based;

e) from disseminating or redistributing to physicians or other medical professionals

any reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on ~~uses of~~ unapproved uses for drugs or medical devices ~~other than those~~ that are approved by FDA for other uses;

f) from suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar program or other symposium regardless of whether ~~uses of~~ unapproved uses for drugs or medical devices ~~other than those~~ that are approved by FDA for other uses are to be discussed.

3. For purposes of this injunction, a "bona fide peer-reviewed journal" is a journal that uses experts to objectively review and select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal.

4. For purposes of this injunction, a "bona fide independent publisher" is a publisher that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer and whose principal business if the publication and distribution of books through normal distribution channels.

5. For purposes of this injunction, an "independent program provider" is an entity that has no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer, that engages in the business of creating and producing continuing medical education seminars, programs or other symposia and that is accredited by a national accrediting

organization pertinent to the topic of the seminars, programs or symposia.

6. Nothing herein shall be construed to limit Defendants' application or enforcement of any rules, regulations, guidances, statutes or other provisions of law that sanction the dissemination or redistribution of any material that is false or misleading. In addition, Defendants may require any pharmaceutical or medical device manufacturer that sponsors or provides financial support for the dissemination or redistribution of articles or reference textbooks or for seminars that include references to ~~uses of~~ unapproved uses for drugs or medical devices ~~other than those~~ that are approved by FDA for other uses to disclose (i) its interest in such drugs or devices, and (ii) the fact that the use discussed has not been approved by FDA.

7. Defendants shall cause this injunction to be published in the Federal Register within ~~30~~ 15 days of the date hereof.

IT IS SO ORDERED on this _____ day of _____, ~~1998~~ 1999.

[Redline Version]
THE HONORABLE ROYCE C. LAMBERTH
United States District Judge

UNITED STATES DISTRICT COURT
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WASHINGTON LEGAL FOUNDATION, Plaintiff, v. MICHAEL FRIEDMAN, in his official capacity as Acting Commissioner, Food and Drug Administration, and DONNA SHALALA, in her official capacity as Secretary, Department of Health and Human Services, Defendants.	)	Civil Action 94-1306 (RCL)

ORDER

Upon consideration of the defendants' motion to alter or amend the judgment and for a stay, the plaintiff's opposition thereto, defendants' reply, and the record herein, and for the reasons set forth in the memorandum opinion issued this date, the defendants' motion is hereby GRANTED in part and DENIED in part.

This Court's Order Granting Summary Judgment and Permanent Injunction, issued July 30, 1998, is hereby AMENDED to clarify that it applies only to unapproved uses of drugs and medical devices approved by the FDA for some other use, not to unapproved drugs and devices. To illustrate this amendment, attached to this order is a Redline Amended Order Granting Summary Judgment and Permanent Injunction, showing precisely what language will be

stricken and what language will be inserted when a final order is issued.

Defendants' request that the Court limit the application of the order and injunction to the Guidance Documents is DENIED.

The defendants shall submit a supplemental brief relating to the FDAMA and its implementing regulations within 20 days of this date. Plaintiff shall file its opposition within 15 days thereafter. Defendant may file a reply within 10 days after plaintiff's opposition. The Court will thereafter issue a Final Amended Order Granting Summary Judgment, and the July 30, 1998 order and injunction will become effective upon issuance of the Final Amended Order.

SO ORDERED.

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Royce C. Lamberth
United States District Judge

DATE: